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By: Stuart McLeish

Stuart McLeish

PATENT
Attorney Docket No.: 16807-001530US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: Unassigned
ROBERT S. BEHL et al.	Art Unit: Unassigned
Application No.: Unassigned	
Filed: Herewith	PRELIMINARY AMENDMENT
For: APPARATUS AND METHOD FOR TREATING TUMORS NEAR THE SURFACE OF AN ORGAN	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments and remarks.

IN THE CLAIMS:

Please cancel claims 1-25. Claim 57 has been amended. Claims 63 and 64 are new.

Claims 1-25 are cancelled.

26. (As filed) A method for heat-mediated necrosis of a target region in tissue, said method comprising:

inhibiting blood flow into the target region, wherein inhibiting comprises creating a blood flow barrier across a tissue boundary or throughout the target region; and

heating the tissue within the target region for a time and of a power level sufficient to necrose said tissue, wherein blood flow inhibition reduces the amount of energy required to heat the tissue.

27. (As filed) A method as in claim 26, wherein inhibiting blood flow comprises heating the tissue at or near a distal boundary of the target region to at least partially block the vasculature leading into and out of the target region.

28. (As filed) A method as in claim 27, wherein the inhibiting step comprises deploying an electrode array proximal the distal boundary and delivering high frequency energy from the array into the tissue.

29. (As filed) A method as in claim 28, wherein heating of the target region comprises engaging a second electrode against an area of tissue overlying the target region and delivering high frequency energy from the electrode to the target region.

30. (As filed) A method as in claim 29, wherein the electrode array and the second electrode are deployed to compress tissue therebetween and further inhibit blood flow into the target region.

31. (As filed) A method as in claim 26, wherein inhibiting blood flow comprises compressing tissue within the target region sufficiently to reduce blood flow therethrough.

32. (As filed) A system for treating a target region in tissue beneath a tissue surface, said system comprising:

a probe having a distal end adapted to be positioned beneath the tissue surface to a site in the tissue;

a plurality of electrodes deployable from the distal end of the probe to span a region of tissue proximate the target region; and

a cover removably attachable to the probe and adapted to span an area of the tissue surface over the target region.

33. (As filed) A system as in claim 32, wherein the cover has a generally flat face.

34. (As filed) A system as in claim 32, wherein the cover has an area in the range from 2 cm^2 to 10 cm^2.

35. (As filed) A system as in claim 32, wherein the cover comprises a surface electrode including a support having an electrode face and an electrically and/or thermally insulated face opposite to the electrode face.

36. (As filed) A system as in claim 35, wherein the surface electrode comprises a plurality of tissue-penetrating elements on the electrode face.

37. (As filed) A system as in claim 36, wherein the surface electrodes comprises from 4 to 16 tissue-penetrating elements.

38. (As filed) A system as in claim 36, wherein the tissue-penetrating elements are pins having a diameter in the range from 1 mm to 3 mm and a depth from the electrode face in the range from 3 mm to 10 mm.

39. (As filed) A system as in claim 32, further comprising a connector on the cover which removably attaches said electrode to the probe.

40. (As filed) A system as in claim 32, further comprising a connector on the cover which is selectively attachable at different axial positions along the probe.

41. (As filed) A system as in claim 36, wherein the surface electrode is adapted to mechanically couple to the probe, wherein the plurality of electrodes and surface electrodes are electrically coupled for monopolar operation.

42. (As filed) A system as in claim 41, wherein the surface electrode is electrically coupled to the probe electrodes when the surface electrode is mounted on the probe.

43. (As filed) A system as in claim 41, wherein the surface electrode is electrically isolated from the probe electrodes when the surface electrode is mounted on the probe.

44. (As filed) A system as in claim 36, wherein the surface electrode is adapted to mechanically couple to the probe, wherein the plurality of electrodes remain electrically isolated from the surface electrode for bipolar operation.

45. (As filed) A system as in claim 32, wherein the probe comprises:

a cannula having a proximal end, a distal end, and a lumen extending to at least the distal end, and wherein the plurality of electrodes are resilient and disposed in the cannula lumen to reciprocate between a proximally retracted position wherein all electrodes are radially constrained within the lumen and a distally extended position wherein all electrodes deploy radially outwardly, said plurality including at least three electrodes.

46. (As filed) A system as in claim 45, wherein at least some of the electrodes are shaped so that they assume an outwardly everted configuration as they are extended distally into tissue from the distal end of the cannula.

47. (As filed) A system as in claim 45, further comprising a rod structure reciprocatably received in cannula lumen, wherein the electrodes are secured at a distal end of the rod in an equally spaced-apart pattern.

48. (As filed) A system as in claim 45, wherein the cannula has a tissue-penetrating member at its distal end to permit advancement of the cannula through tissue.

49. (As filed) A system as in claim 45, further comprising a stylet reciprocatably received in the cannula lumen, wherein the stylet may be used for initially positioning the cannula in tissue and thereafter exchanged with the electrodes.

50. (As filed) A system as in claim 45, wherein the cannula has a length in the range from 5 cm to 30 cm and an outer diameter in the range from 1 mm to 5 mm.

51. (As filed) A system as in claim 45, wherein the electrodes deploy outwardly to a radius in the range from 0.5 cm to 3 cm when fully distally extended from the cannula.

52. (As filed) A system as in claim 45, wherein the plurality includes at least five electrodes.

53. (As filed) A system as in claim 45, wherein the plurality includes at least eight electrodes.

54. (As filed) A system as in claim 45, wherein the plurality includes at least ten electrodes.

55. (As filed) A system as in claim 36, wherein the active areas of the first electrode array and the second electrode are approximately equal and the first electrode array and second electrode are electrically isolated.

56. (As filed) A surface electrode comprising:

a support structure attachable to an elongate probe and having an area in the range from 2 cm^2 to 10 cm^2;

4 to 16 tissue-penetrating pin electrodes projecting from the support structure and having a length in the range from 3 mm to 10 mm and a diameter in the range from 1 mm to 3 mm.

57. (Amended) A kit comprising:

an electrode or cover adapted to be engaged against a tissue surface; and

instructions for treating a target region in tissue using the electrode in combination with an electrode array, the target region at or beneath a tissue surface, the instructions comprising:

deploying a first array of electrodes in the tissue at the target region;

deploying a second electrode on the tissue surface over the target region; and

applying electrical current to the tissue through the electrodes.

58. (As filed) A kit as in claim 57, further comprising the electrode array.

59. (As filed) In a method for applying high frequency electrical energy to tissue a target region beneath a tissue surface, an improvement comprising compressing the target region sufficiently to inhibit blood flow therethrough while high frequency electrical energy is being applied.

60. (As filed) A method as in claim 59, wherein the target region is compressed between a first array of electrodes beneath the tissue surface and a cover or second electrode on the tissue surface.

61. (As filed) A method as in claim 59, wherein the target region is compressed between a pair of spaced-apart structures which are both penetrated into the tissue.

62. (As filed) A method for positioning an electrode array beneath a tissue surface, said method comprising:

determining a target depth;

positioning a cover on a tissue-penetrating probe so that an array deployment location on the probe is located away from the cover by a distance corresponding to the target depth;

penetrating the probe into tissue until the cover engages the tissue surface; and

deploying the electrode array from the deployment location.

63. (New) A kit comprising:

an electrode or cover adapted to be engaged against a tissue surface; and

instructions for treating a target region in tissue using the electrode in combination with an electrode array, the target region at or beneath a tissue surface the instructions comprising:

deploying a first array of electrodes in the tissue at the target region;

deploying a cover over the tissue surface over the target region, wherein the first array and cover are drawn together to apply compression on tissue in the target region; and

applying electrical current to tissue in the target region through the first array of electrodes.

64. (New) A kit comprising:

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instructions for treating a target region in tissue using the electrode in combination with an electrode array, the target region at or beneath a tissue surface the instructions comprising:

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deploying a cover over the tissue surface over the target region, wherein the cover is configured to electrically and thermally isolate the target region and first electrode array from external tissue structures adjacent to the target region; and

applying electrical current to tissue in the target region through the first array of electrodes.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

PATENT

Attached is a marked up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

James M. Heslin
Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JMH:kab
PA 3138944 v1

VERSION WITH MARKINGS TO SHOW CHANGES MADE.

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44. (As filed) A system as in claim 36, wherein the surface electrode is adapted to mechanically couple to the probe, wherein the plurality of electrodes remain electrically isolated from the surface electrode for bipolar operation.

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a cannula having a proximal end, a distal end, and a lumen extending to at least the distal end, and wherein the plurality of electrodes are resilient and disposed in the cannula lumen to reciprocate between a proximally retracted position wherein all electrodes are radially constrained within the lumen and a distally extended position wherein all electrodes deploy radially outwardly, said plurality including at least three electrodes.

46. (As filed) A system as in claim 45, wherein at least some of the electrodes are shaped so that they assume an outwardly everted configuration as they are extended distally into tissue from the distal end of the cannula.

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57. (Amended) A kit comprising:

an electrode or cover adapted to be engaged against a tissue surface; and

instructions for treating a target region in tissue using the electrode in combination with an electrode array, the target region at or beneath a tissue surface, the instructions comprising:

deploying a first array of electrodes in the tissue at the target region;

deploying a second electrode on the tissue surface over the target region; and

applying electrical current to the tissue through the electrodes, according to any of claims 1, 2, or 3 **[according to any of claims 1, 2, or 3]**.

58. (As filed) A kit as in claim 57, further comprising the electrode array.

59. (As filed) In a method for applying high frequency electrical energy to tissue a target region beneath a tissue surface, an improvement comprising compressing the target region sufficiently to inhibit blood flow therethrough while high frequency electrical energy is being applied.

60. (As filed) A method as in claim 59, wherein the target region is compressed between a first array of electrodes beneath the tissue surface and a cover or second electrode on the tissue surface.

61. (As filed) A method as in claim 59, wherein the target region is compressed between a pair of spaced-apart structures which are both penetrated into the tissue.

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determining a target depth;

positioning a cover on a tissue-penetrating probe so that an array deployment location on the probe is located away from the cover by a distance corresponding to the target depth;

penetrating the probe into tissue until the cover engages the tissue surface; and

deploying the electrode array from the deployment location.

63. (New) A kit comprising:

an electrode or cover adapted to be engaged against a tissue surface; and

instructions for treating a target region in tissue using the electrode in combination with an electrode array, the target region at or beneath a tissue surface the instructions comprising:

deploying a first array of electrodes in the tissue at the target region;

deploying a cover over the tissue surface over the target region, wherein the first array and cover are drawn together to apply compression on tissue in the target region; and

applying electrical current to tissue in the target region through the first array of electrodes.

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deploying a cover over the tissue surface over the target region, wherein the cover is configured to electrically and thermally isolate the target region and first electrode array from external tissue structures adjacent to the target region; and

applying electrical current to tissue in the target region through the first array of electrodes.